

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|-------------------------|------------------|
| 09/834,747 | 04/13/2001 | Hal Sternberg | BIOT008 | 4271 |
| 24353 | 7590 03/21/2003 | | | |
| BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 | | | EXAMINER | |
| | | | CHOI, FRANK I | |
| MENLO PARK, CA 94025 | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |
| | | | DATE MAILED: 03/21/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | |
|---|--|--|--|--|
| Advisory Action | 09/834,747 | STERNBERG, HAL | | |
| Auvisory Action | Examiner | Art Unit | | |
| | Frank I Choi | 1616 | | |
| The MAILING DATE of this communication appe | ars on the c ver sheet with the c | orrespondence address | | |
| THE REPLY FILED 11 March 2003 FAILS TO PLACE TO THE REPLY FILED 11 March 2003 FAILS TO PLACE TO THE REPLY FILED 11 March 2003 FAILS TO PLACE TO Extend to avoicinal rejection under 37 CFR 1.113 may only be either: (1) condition for allowance; (2) a timely filed Notice of Appea Examination (RCE) in compliance with 37 CFR 1.114. | oid abandonment of this application at the contract of the con | ntion. A proper reply to a | | |
| PERIOD FOR RE | PLY [check either a) or b)] | | | |
| a) The period for reply expires <u>3</u> months from the mailing date | | to the first rejection which we is letter. In | | |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire I ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The fee have been filed is the date for purposes of determining the period of the under 37 CFR 1.17(a) is calculated from: (1) the expiration date of (2) as set forth in (b) above, if checked. Any reply received by the Officinely filed, may reduce any earned patent term adjustment. See 37 C | ater than SIX MONTHS from the mailing FILED WITHIN TWO MONTHS OF THe date on which the petition under 37 CF of extension and the corresponding amo the shortened statutory period for reply ce later than three months after the mail | g date of the final rejection. HE FINAL REJECTION. See MPEP R 1.136(a) and the appropriate extension unt of the fee. The appropriate extension originally set in the final Office action; or | | |
| 1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. | | | | |
| 2. The proposed amendment(s) will not be entered be | ecause: | | | |
| (a) X they raise new issues that would require further | er consideration and/or search (| see NOTE below); | | |
| (b) M they raise the issue of new matter (see Note b | pelow); | | | |
| (c) they are not deemed to place the application in issues for appeal; and/or | n better form for appeal by mate | rially reducing or simplifying the | | |
| (d) they present additional claims without canceli | ng a corresponding number of f | nally rejected claims. | | |
| NOTE: See Continuation Sheet. | | | | |
| Applicant's reply has overcome the following rejection | on(s): | | | |
| 4. Newly proposed or amended claim(s) would canceling the non-allowable claim(s). | be allowable if submitted in a se | eparate, timely filed amendment | | |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for application in condition for allowance because: Se | | dered but does NOT place the | | |
| 6. The affidavit or exhibit will NOT be considered bec raised by the Examiner in the final rejection. | ause it is not directed SOLELY t | o issues which were newly | | |
| 7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we | | | | |
| The status of the claim(s) is (or will be) as follows: | | | | |
| Claim(s) allowed: | | | | |
| Claim(s) objected to: | | | | |
| Claim(s) rejected: | | <i>'</i> | | |
| Claim(s) withdrawn from consideration: | | | | |
| 8 The proposed drawing correction filed on is | a) approved or b) disapp | roved by the Examiner. | | |
| 9. Note the attached Information Disclosure-Statemen | nt(s)(PTO-1449) Paper No(s) | · · · · · · · · · · · · · · · · · · · | | |
| 10. Other: OTHER PRIMARY EXAMINER GROUP 1000 | | ARA | | |

Continuation Sheet (PTO-303)



Continuation of 2. NOTE: Applicant now proposes to exclude sodium bicarbonate as a pharmacological means for reducing the CO2 level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia which amendment was not made previously and was specifically required in at least the method claims. As such, said amendment appears to raise new issues which would require further consideration and/or search. Also, said amendment appears to raise the issue of new matter as the Specification does not indicate that sodium bicarbonate may be excluded from the pharmacological means.

Continuation of 5. does NOT place the application in condition for allowance because: the proposed amendments have not been entered. However, should they be entered the following applies: The proposed amendment would overcome the 35 USC 112, 2nd paragraph rejection of claims 14 and 18, would overcome the rejection of claims 1-25 over Taylor (US 5,514,536) based on Applicant's arguments relative to the exclusion of conventional biological buffers as specifically defined by Applicant's specification but not as to Applicant's arguments relative to refuting inherency. With respect to the rejection of claims 1-25 over Segall et al. ('880 or '801), Examine has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below. Applicant's exclusion of sodium bicarbonate is directed to pharmacological means for reducing CO2 level in an amount sufficient to reduce the risk of acidosis/acidemia, however, the prior art does not indicate that the sodium bicarbonate is used to reduce CO2 levels and Applicant does not appear to have offered any evidence which shows that sodium bicarbonate reduces CO2 levels. As such, the negative limitation does not appear to include exclusion of the use of sodium bicarbonate as disclosed in the prior art. Applicant's arguments relative to oxygenators does not appear to be supported by probative evidence (See In re Schulze, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) (attorney arguments do not constitute evidence)). The fact remains that the prior art oxygenator appears to be the same device described by Applicant to be suitable for the claimed method. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 231 USPQ 136 (Fed. Cir. 1986) Further, the expressly disclosed methods also involve the use of anesthetics which are specifically recited as pharmacological means of reducing the CO2 level. Applicant does no appear to have shown that the expressly disclosed methods do not inherently reduce CO2 levels sufficient to reduce the risk of acidosis/acidemia. Applicant's claims indicate that the risk of acidosis/acidemia is reduced, as such, acidosis/acidemia may still occur. As such, the fact that the prior art teaches that sodium bicarbonate may opitionally be used to manage acidosis does not appear to overcome inherency rejection. Finally, Applicant appears to exclude oxygenators from the definition of pharmacological means. However pharmacological means is defined to include any means in which a pharmacological agent is employed to achieve the desired reduction o CO2 level. Oxygen is clearly a pharmacological agent, as such, the use of oxygenators does not appear to be excluded by the limitation "pharmacological means".